

Application No. 10/085,731  
Amendment dated January 21, 2005  
Reply to Office Action of July 21, 2004

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1. (currently amended) A guard for use in human interbody spinal surgery from across a disc space between two adjacent vertebral bodies, comprising:  
a body having a leading end and an opposite-a trailing end, said body having a first portion and a second portion in pivotal relationship to one another proximate said leading end between an open position and a closed position, said first and second portions having opposed interior portions being at least in part flat, respectively, said first and second portions defining an opening for providing a protected pathway access to the disc space and the adjacent vertebral bodies, said opposed interior portions being adapted to guide therethrough a bone removal device sized to form an implantation space across the disc space and at least in part into the adjacent vertebral bodies; and  
at least one disc space penetrating extension extending from said leading end of said body adapted for insertion at least in part into the disc space, said extension having a first portion extending from said first portion of said body, said first portion of said extension having a contact surface adapted to bear against one of the adjacent endplates of the adjacent vertebral bodies, said extension having a second portion extending from said second portion of said body, said second portion of said extension having a contact surface adapted to bear against the other of the adjacent endplates of the adjacent vertebral bodies, said contact surfaces of said first and second portions being in pivotal relationship to one another from an insertion position to a deployed position to move the adjacent vertebral bodies apart upon movement of said first and second portions of said body from the open position to the closed position, said contact surfaces of said first and second portions being pivotal about an axis that passes through

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- at least a portion of the pathway to the disc space and the adjacent vertebral bodies.
2. (original) The guard of claim 1, wherein said opposed interior portions of said first and second portions of said body are parallel to one another when said body is in the closed position.
  3. (original) The guard of claim 1, wherein said opposed interior portions of said first and second portions of said body are angled to one another when said body is in the open position.
  4. (original) The guard of claim 1, wherein said opening defined by said first and second portions of said body is generally rectangular.
  5. (currently amended) The guard of claim 1, wherein said opening defined by said first and second portions of said body is generally square.
  6. (original) The guard of claim 1, wherein said body has an exterior surface that has opposed upper and lower surfaces oriented toward the adjacent vertebral bodies, respectively, said upper and lower surfaces being at least in part flat.
  7. (original) The guard of claim 6, wherein at least a portion of said upper and lower surfaces of said exterior surface are parallel to one another when said body is in the closed position.
  8. (original) The guard of claim 6, wherein at least a portion of said upper and lower surfaces of said exterior surface are angled to one another when said body is in the open position.
  9. (original) The guard of claim 6, wherein said exterior surface of said body has opposed side surfaces, said side surfaces being at least in part flat.
  10. (original) The guard of claim 9, wherein said side surfaces of said exterior surface are parallel to one another.
  11. (original) The guard of claim 1, wherein said body has an exterior surface that has a generally rectangular cross section along at least a portion of the length of said body.
  12. (original) The guard of claim 1, wherein said body has an exterior surface that has a generally square cross section along at least a portion of the length of said body.

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13. (original) The guard of claim 1, wherein said body has a generally rectangular cross section along at least a portion of the length of the guard.
14. (original) The guard of claim 1, wherein said body has a generally square cross section along at least a portion of the length of the guard.
15. (original) The guard of claim 1, wherein said first and second portions of said body cooperatively engage along the length of the body when in the closed position.
16. (original) The guard of claim 1, wherein said first and second portions of said body when in the closed position form a tube.
17. (original) The guard of claim 1, wherein said leading end of said body is adapted to conform at least in part to the exterior surface of the adjacent vertebral bodies.
18. (original) The guard of claim 1, wherein leading end of said body is cutback to permit the curvature of the two adjacent vertebral bodies to have an intimate fit between said body and the two adjacent vertebral bodies when said contact surfaces are in the deployed position.
19. (original) The guard of claim 1, wherein said first and second portions of said extension touch one another when in the insertion position.
20. (original) The guard of claim 1, wherein said extension has a height between said contact surfaces and a length sufficient to properly align and distance apart the adjacent vertebral bodies when in the deployed position.
21. (original) The guard of claim 20, wherein said contact surfaces have a length greater than one half the depth of the disc space measured from the anterior to posterior aspect of the adjacent vertebral bodies.
22. (original) The guard of claim 1, wherein said contact surfaces are parallel to each other along a substantial portion of the length thereof when in the insertion position.

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23. (original) The guard of claim 1, wherein said body has an external surface at its leading end and said extension has an external surface that is at least in part coextensive with said external surface of said body.
24. (original) The guard of claim 1, wherein said extension has a tapered leading end to facilitate placement of said extension into the disc space when in the insertion position.
25. (original) The guard of claim 1, further comprising at least a second disc space penetrating extension extending from said leading end of said body.
26. (original) The guard of claim 25, wherein said extensions are diametrically opposed to each other and spaced apart from one another to provide access to the adjacent vertebral bodies from within the disc space.
27. (original) The guard of claim 26, wherein said extensions have the same height.
28. (original) The guard of claim 26, wherein said extensions have the same height at the same distance along their length from said body.
29. (currently amended) The guard of claim 1, wherein said opposed-contacting surfaces diverge away from said body along at least a portion of their length.
30. (original) The guard of claim 1, wherein said body has at least one window adapted to permit portions of bone extending through said window to be removed by the bone removal device passing through said body.
31. (currently amended) The guard of claim 1, wherein said body has at least one window adapted to permit the surgeon to observe the surgery through said window.
32. (original) The guard of claim 1, wherein said first and second portions of said body are hinged to one another to rotatably articulate relative to one another.
33. (original) The guard of claim 1, wherein said first and second portions of said body rotatably articulate relative to one another about an axis of rotation that is fixed relative to the mid-longitudinal axis of said guard when moved from the open position to the closed position.
34. (original) The guard of claim 1, further comprising an impaction cap adapted to cooperatively engage said trailing end of said body when said body is in the open position.

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35. (original) The guard of claim 1, further comprising a lock adapted to cooperatively engage said body of said guard when said body is in the closed position to hold said body in the closed position.
36. (original) The guard of claim 35, wherein said lock is a collar adapted to cooperatively engage said body of said guard when said body is in the closed position to hold said body in the closed position.
37. (original) The guard of claim 36, wherein said collar cooperatively engages said trailing end of said body of said guard.
38. (original) The guard of claim 1, wherein said body has an interior having a cooperating surface for guiding a corresponding cooperating surface on the bone removal device.
39. (original) The guard of claim 1, wherein said body has a height in the range of 8-25 mm.
40. (currently amended) The guard of claim 1, wherein said opening defined by said first and second portions of said body has a height in the range of 8-20 mm.
41. (original) The guard of claim 1, wherein said opening defined by said first and second portions of said body has a width in the range of 10-25 mm.
42. (original) The guard of claim 1, wherein said extension has a combined height when closed in the range of 6-18 mm.
43. (original) The guard of claim 1, wherein said extension has a length in the range of 12-32 mm.
44. (original) The guard of claim 1, in combination with a bone removal device for forming through said guard an implantation space across the disc space.
45. (original) The guard of claim 44, wherein said bone removal device is selected from the group consisting of a drill, a trephine, a reamer, an end mill, a chisel, a burr, a rongeur, an osteotome, and an abrader.

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46. (original) The guard of claim 44, wherein said bone removal device has a working end adapted for insertion into the spine, said working end having at least two cutters selected to create a predetermined surface contour into each of the adjacent vertebral bodies as said working end is moved.
47. (original) The guard of claim 46, wherein said cutters are adapted to simultaneously create predetermined surface contours on the respective end plates of the adjacent vertebral bodies.
48. (original) The guard of claim 46, wherein said working end includes a leading edge configured as a bone-cutting surface.
49. (original) The guard of claim 46, wherein said cutters are configured to be generally parallel to the surface contour formed in the vertebral body as said working end is moved.
50. (original) The guard of claim 44, wherein said bone removal device has a height in the range of 8-20 mm and a width in the range of 10-25 mm.
51. (original) The guard of claim 1, in combination with an implant driver sized in part for passage through said opening for passing an implant through said guard and into the disc space.
52. (original) The guard of claim 51, wherein said implant driver comprises a shaft adapted to engage the implant at one end and a handle for manipulating said implant driver at the other end of said shaft.
53. (original) The guard of claim 1, in combination with a spinal implant adapted to be inserted in the implantation space formed through said guard.
54. (original) The guard of claim 1, in combination with an implant sized and shaped to at least in part match the space formed in the spine by the bone removal device.
55. (original) The guard of claim 53, wherein said implant comprises at least one of bone and bone growth promoting material.
56. (original) The guard of claim 55, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix,

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ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.

57. (original) The guard of claim 53, wherein said implant is in combination with a bone growth promoting material.
58. (original) The guard of claim 57, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
59. (original) The guard of claim 53, wherein said implant is treated with a bone growth promoting substance.
60. (original) The guard of claim 53, wherein said implant comprises at least one of the following materials: metal, titanium, plastic, and ceramic appropriate for implantation in the human body.
61. (original) The guard of claim 53, wherein said implant is at least in part resorbable.
62. (original) The guard of claim 53, wherein said implant is formed of a porous material.
63. (original) The guard of claim 53, in combination with a chemical substance adapted to inhibit scar formation.
64. (original) The guard of claim 53, in combination with an antimicrobial material.
65. (currently amended) A guard for use in human interbody spinal surgery from across a disc space between two adjacent vertebral bodies, comprising:

a body having an opening for providing a protected pathway to the disc space and the adjacent vertebral bodies, said opening having at least in part opposed interior portions being at least in part flat adapted to guide therethrough a bone removal device sized to form an implantation space across the disc space and at least in part into the adjacent vertebral bodies; and

at least one disc space penetrating extension extending from said body adapted for insertion at least in part into the disc space, said disc penetrating extension having a first portion having a contact surface adapted to bear against one of the adjacent endplates of the adjacent vertebral bodies and a second

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portion having a contact surface adapted to bear against the other of the adjacent endplates of the adjacent vertebral bodies, said contact surfaces of said first and second portions being rotatably articulating relative to one another between an insertion position and a deployed position to move the adjacent vertebral bodies apart, said contact surfaces of said first and second portions being pivotal about an axis that passes through at least a portion of the pathway to the disc space and the adjacent vertebral bodies.

66. (original) The guard of claim 65, wherein said opposed interior portions of said opening are parallel to one another.
67. (original) The guard of claim 65, wherein said opposed interior portions of said opening are angled to one another.
68. (original) The guard of claim 65, wherein said opening of said body is generally rectangular.
69. (original) The guard of claim 65, wherein said opening of said body is generally square.
70. (original) The guard of claim 65, wherein said body has an exterior surface that has opposed upper and lower surfaces oriented toward the adjacent vertebral bodies, respectively, said upper and lower surfaces being at least in part flat.
71. (original) The guard of claim 70, wherein said exterior surface of said body has opposed side surfaces, said side surfaces being at least in part flat.
72. (original) The guard of claim 71, wherein said side surfaces of said exterior surface are parallel to one another.
73. (original) The guard of claim 65, wherein said body has an exterior surface that has a generally rectangular cross section along at least a portion of the length of said body.
74. (original) The guard of claim 65, wherein said body has an exterior surface that has a generally square cross section along at least a portion of the length of said body.
75. (original) The guard of claim 65, wherein said body has a generally rectangular cross section along at least a portion of the length of the guard.

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76. (original) The guard of claim 65, wherein said body has a generally square cross section along at least a portion of the length of the guard.
77. (original) The guard of claim 65, wherein said body has a leading end adapted to conform at least in part to the exterior surface of the adjacent vertebral bodies.
78. (original) The guard of claim 65, wherein said body has a leading end that is cutback to permit the curvature of the two adjacent vertebral bodies to have an intimate fit between said body and the two adjacent vertebral bodies when said contact surfaces are in the deployed position.
79. (original) The guard of claim 65, wherein said first and second portions of said extension touch one another when in the insertion position.
80. (original) The guard of claim 65, wherein said extension has a height between said contact surfaces and a length sufficient to properly align and distance apart the adjacent vertebral bodies when in the deployed position.
81. (original) The guard of claim 80, wherein said contact surfaces have a length greater than one half the depth of the disc space measured from the anterior to posterior aspect of the adjacent vertebral bodies.
82. (original) The guard of claim 65, wherein said contact surfaces are parallel to each other along a substantial portion of the length therecf when in the insertion position.
83. (original) The guard of claim 65, wherein said body has an external surface and said extension has an external surface that is at least in part coextensive with said external surface of said body.
84. (original) The guard of claim 65, wherein said extension has a tapered leading end to facilitate placement of said extension into the disc space when in the insertion position.
85. (original) The guard of claim 65, further comprising at least a second disc space penetrating extension extending from said body.

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86. (original) The guard of claim 85, wherein said extensions are diametrically opposed to each other and spaced apart from one another to provide access to the adjacent vertebral bodies from within the disc space.
87. (original) The guard of claim 86, wherein said extensions have the same height.
88. (original) The guard of claim 86, wherein said extensions have the same height at the same distance along their length from said body.
89. (currently amended) The guard of claim 65, wherein said opposed-contacting surfaces diverge away from said body along at least a portion of their length.
90. (original) The guard of claim 65, wherein said body has at least one window adapted to permit portions of bone extending through said window to be removed by the bone removal device passing through said body.
91. (original) The guard of claim 65, wherein said body has at least one window adapted to permit the surgeon to observe the surgery through said window.
92. (original) The guard of claim 65, wherein said first and second portions of said disc space penetrating extension are hinged to one another to rotatably articulate relative to one another.
93. (original) The guard of claim 65, wherein said first and second portions of said disc space penetrating extension rotatably articulate relative to one another about an axis of rotation that is fixed relative to the mid-longitudinal axis of said guard when moved from the insertion position to the deployed position.
94. (original) The guard of claim 65, further comprising an impaction cap adapted to cooperatively engage a trailing end of said body.
95. (original) The guard of claim 65, wherein said body has an interior having a cooperating surface for guiding a corresponding cooperating surface on the bone removal device.
96. (original) The guard of claim 65, wherein said body has a height in the range of 8-25 mm.
97. (currently amended) The guard of claim 65, wherein said opening of said body has a height in the range of 8-20 mm.
98. (original) The guard of claim 65, wherein said opening of said body has a width in the range of 10-25 mm.

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99. (original) The guard of claim 65, wherein said extension has a combined height when closed in the range of 6-18 mm.
100. (original) The guard of claim 65, wherein said extension has a length in the range of 12-32 mm.
101. (original) The guard of claim 65, in combination with a bone removal device for forming through said guard an implantation space across the disc space.
102. (original) The guard of claim 101, wherein said bone removal device is selected from the group consisting of a drill, a trephine, a reamer, an end mill, a chisel, a burr, a rongeur, an osteotome, and an abrader.
103. (original) The guard of claim 101, wherein said bone removal device has a working end adapted for insertion into the spine, said working end having at least two cutters selected to create a predetermined surface contour into each of the adjacent vertebral bodies as said working end is moved.
104. (original) The guard of claim 103, wherein said cutters are adapted to simultaneously create predetermined surface contours on the respective end plates of the adjacent vertebral bodies.
105. (original) The guard of claim 103, wherein said working end includes a leading edge configured as a bone-cutting surface.
106. (original) The guard of claim 103, wherein said cutters are configured to be generally parallel to the surface contour formed in the vertebral body as said working end is moved.
107. (original) The guard of claim 101, wherein said bone removal device has a height in the range of 8-20 mm and a width in the range of 10-25 mm.
108. (original) The guard of claim 65, in combination with an implant driver sized in part for passage through said opening for passing an implant through said guard and into the disc space.
109. (original) The guard of claim 108, wherein said implant driver comprises a shaft adapted to engage the implant at one end and a handle for manipulating said implant driver at the other end of said shaft.
110. (original) The guard of claim 65, in combination with a spinal implant adapted to be inserted in the implantation space formed through said guard.

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111. (original) The guard of claim 65, in combination with an implant sized and shaped to at least in part match the space formed in the spine by the bone removal device.
  112. (original) The guard of claim 110, wherein said implant comprises at least one of bone and bone growth promoting material.
  113. (original) The guard of claim 112, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins, bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
  114. (original) The guard of claim 110, wherein said implant is in combination with a bone growth promoting material.
  115. (original) The guard of claim 114, wherein said bone growth promoting material is selected from one of bone, bone derived products, demineralized bone matrix, ossifying proteins bone morphogenetic protein, hydroxyapatite, and genes coding for the production of bone.
  116. (original) The guard of claim 110, wherein said implant is treated with a bone growth promoting substance.
  117. (original) The guard of claim 110, wherein said implant comprises at least one of the following materials: metal, titanium, plastic, and ceramic appropriate for implantation in the human body.
  118. (original) The guard of claim 110, wherein said implant is at least in part resorbable.
  119. (original) The guard of claim 110, wherein said implant is formed of a porous material.
  120. (original) The guard of claim 110, in combination with a chemical substance adapted to inhibit scar formation.
  121. (original) The guard of claim 110, in combination with an antimicrobial material.
- Claims 122-165 (cancelled).
166. (new) The guard of claim 1, wherein the axis about which said contact surfaces pivot intersects the mid-longitudinal axis of said guard.

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167. (new) The guard of claim 1, wherein the axis about which said contact surfaces pivot is substantially perpendicular to the sagittal axis of the spine when said guard is engaged to the spine.
168. (new) The guard of claim 1, wherein said extension has a height between said contact surfaces, said contact surfaces of said first and second portions being opposite one another along the height of said extension.
169. (new) The guard of claim 65, wherein the axis about which said contact surfaces pivot intersects the mid-longitudinal axis of said guard.
170. (new) The guard of claim 65, wherein the axis about which said contact surfaces pivot is substantially perpendicular to the sagittal axis of the spine when said guard is engaged to the spine.
171. (new) The guard of claim 65, wherein said extension has a height between said contact surfaces, said contact surfaces of said first and second portions being opposite one another along the height of said extension.